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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,394	10/18/2001	Celia Briscoe	P32221	8887

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EXAMINER

MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,394

Applicant(s)

BRISCOE, CELIA

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-11 are pending in this application.

Title

Applicant should avoid the use of novel in the title as patents are presumed to be novel and unobvious. Furthermore, the title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

Claim 4 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 5-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation (*United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is required is not based on a single factor but is rather a conclusion reached by weighing many factors (See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter, 1986) and *In re Wands*, 8USPQ2d 1400 (Fed. Cir. 1988); these factors include the following:

- 1) Unpredictability of the art. This invention recites a method for the detection of a compound that mimics, potentiates or inhibits the physiological effect of the ob-protein. The invention proposes as a method assessing the effect of the compound upon an ob-protein activated signal transducer and activator (STAT) DNA response element in an ob-responsive cell line. The method steps are designed to measure the effects of a compound upon a STAT response element wherein the connection between this event and the physiological effects of the ob-protein are unknown. The invention is therefore highly unpredictable.
- 2) State of the art. The state of the art at the time of invention had not provided for reporter gene activity to provide a measure of the physiological effects of a protein. The method steps of providing a cell with a DNA binding elements linked to a reporter gene are used in the art to provide quantitative insight into compounds that can inhibit or stimulate the promoter element or response element. The method steps do not in turn provide information about compounds that mimic or potentiate or inhibit the physiological effects of the ob-protein as these effects are not measured by the invention.

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3) Number of working examples. The specification provides by way of example, a general procedure involving measuring luciferase or b-galactosidase following addition of a compound or an antagonist. The method steps provided include transfecting ob-responsive cells with a STAT element upstream of a minimal promoter and then treat with a compound and measure reporter gene activity.

4) Amount of guidance provided by applicants. The specification discloses that ob-protein is a secreted hormone that acts as a signal from adipose tissue to other organs to regulate weight and energy balance (page 1, line 6-8) by interacting with a membrane bound receptor that activates a JAK-STAT kinase cascade. Activated STAT then binds response elements that in the invention are bound to a reporter gene whose activity is measured. The applicant does not provide guidance as to how a measure of a reporter gene activated by a compound provides a measure of the physiological effects of the ob-protein.

5) Nature of invention. The invention relates to molecular engineering of DNA for pharmaceutical screening of compounds.

6) Level of skill in the art. The level of skill in the art covering the basic method steps of the invention is high. However, the ability to mimic the physiological effects of a protein by measuring its transcription-inducing activity on a response element is not high.

7) Scope of the invention. This invention has broad scope in that it recites a set of method steps designed to detect any compound that mimics, potentiates or inhibits the effect of ob-protein on a STAT response element in endothelium derived cell lines.

Given the above analysis of the factors which the courts have determined are critical in determining whether a claimed invention is enabled, it must be concluded that the skilled artisan

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would have had to have conducted undue experimentation and excessive experimentation in order to practice the claimed invention.

Claim 3 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the specific cells, ECV304, HUVEC, HUAEC, HAEC, HPAEC, HDMECa and HDNECn are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. Neither the instant application nor the prior art teaches the skilled artisan how to reproducibly generate the recited cell lines. The invention does not recite use of any endothelium-derived cells but instead specifically claims ECV304, HUVEC, HUAEC, HAEC, HPAEC, HDMECa and HDNECn. The ECV304, HUVEC, HUAEC, HAEC, HPAEC, HDMECa and HDNECn cells were apparently deposited by others, however their availability in an unrestricted form for the life of a patent issued on the instant application cannot be ensured. Applicants must therefore themselves deposit the specific ECV304, HUVEC, HUAEC, HAEC, HPAEC, HDMECa and HDNECn cells recited in the claims and thus satisfy the deposit requirement under 37 CFR 1.801-1.809 (see enclosed Suggestion for deposit of biological material).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 5-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "the polypeptide" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 8, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Use of the phrase "endothelium derived cells" and "endothelium derived cell lines" in claim 1, and 7-11, is unclear. The specification does not provide guidance as to how the claimed endothelial derived cells or cell lines were derived from the original endothelial cells nor for how closely related the derived cells are to the starting material. Therefore, the metes and bounds of this claim cannot be established and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention

Claims 1-3 and 5-11 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how measuring reporter gene activity allows for detecting compounds that mimic, potentiate or inhibit the physiological effect of the ob-protein.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0196.

Maria B Marvich, PhD
Examiner
Art Unit 1636

February 10, 2003

DAVID GUZO
PRIMARY EXAMINER
